K062873

MAR 2 0 2007

510 (k) Summary
of Safety and Effectiveness

This submission covers the SunPolar Netex Medical stockings which fall under the device classification of medical support stockings (21 CFR 880.5780). The SunPolar Netex Medical Stockings are equivalent to the Jobst Travel Sock (K032325).

Both products are produced on circular knit machines and are made of nylon and spandex yarns. They provide similar compression at the ankle. This submission covers the indication that compression stockings in the 20-40mmHg range can help to prevent the pooling of blood in the legs and apply controlled pressure to the legs.

The product being submitted is substantially equivalent to the predicate product in the materials used, mode of action, and indications for use, and can therefore be considered as safe and effective as the predicate product.

Date: January 22, 2007

Prepared by: James Wang
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544 Fairways Circle
St. Louis, MO 63141-7521
Phone: (314) 432-5656

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James Wang
Director
E.C.I (USA) Corporation
544 Fairways Circle
Saint. Louis, Missouri 63141

MAR 2 0 2007

Re: K062873
Trade/Device Name: Medical Support Stocking (Brand Name SunPolar Netex Stockings)
Regulation Number: 880.5780
Regulation Name: Medical Support Stocking
Regulatory Class: II
Product Code: DWL
Dated: January 30, 2007
Received: February 12, 2007

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

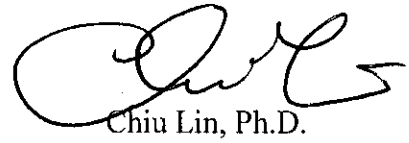
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062873

Device Name: Medical Support Stocking (brand name SunPolar Netex Stockings)

Indications for Use:

Helps to prevent the pooling of blood in the legs and apply controlled pressure to the legs.

Over the Counter

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman for Tom 3/20/07

K062873